

OMEPRAZOLE MAGNESIUM- omeprazole magnesium 20.6mg capsules capsule, delayed release

The Kroger Co.

Active ingredient

Omeprazole magnesium delayed-release capsule 20.6 mg
(equivalent to 20 mg omeprazole)

Purpose

Acid reducer

Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert: Do not use if you are allergic to omeprazole

Do not use if you have

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**

These may be signs of a serious condition. See your Doctor.

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if

you are taking

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- prescription antiretrovirals (medicines for HIV infection)
- methotrexate (arthritis medicine)

Stop use and ask doctor if

- your heartburn continues or worsens

- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea

Pregnancy/Breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours.

14- day Course of Treatment

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew or crush capsules.

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Other information

- read the directions and warnings before use
- keep the carton. It contains important information

Storage

- store at 20 – 25°C (68 – 77° F) and protect from moisture

Inactive ingredients

black iron oxide, dibasic calcium phosphate, gelatin, glyceryl monostearate, hypromellose 3 cps, magnesium oxide, magnesium stearate, methacrylic acid copolymer dispersion, methacrylic acid copolymer Type B, microcrystalline cellulose, polysorbate 80, potassium hydroxide, propylene glycol, red iron oxide, shellac, silicon dioxide, sodium lauryl sulphate, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions

Call **1-888-375-3784**

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

PRINCIPAL DISPLAY PANEL

Kroger Treats Frequent Heartburn Occurring 2 or More Days a Week

Omeprazole Magnesium
Delayed-Release Capsules 20.6 mg
ACID REDUCER
ONE 14-Day Course of Treatment
14 SAFETY SEALED CAPSULES

IMPORTANT: This label does not contain full product information. See carton for complete information. Read the directions and warnings before use. Retain carton for reference.

Active Ingredient Purpose (in each capsule)
Omeprazole magnesium delayed-release capsule 20.6 mg Acid reducer (equivalent to 20mg omeprazole)

Use
■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Other Information
■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store at 20-25°C (68-77°F) and protect from moisture

Questions? 1-800-632-6900

TAMPER EVIDENT: Do not use if foil seal under cap printed with "sealed for your protection" or pink band around center of capsule are broken or missing.

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CINCINNATI, OHIO 45202
QUALITY GUARANTEE
www.kroger.com

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Omeprazole Magnesium Delayed-Release Capsules, 20.6 mg - Container Label and carton 42 count

OMEPRAZOLE MAGNESIUM

omeprazole magnesium 20.6mg capsules capsule, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59450-012(NDC:55111-397)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (omeprazole - UNII:KG60484QX9)	omeprazole	20 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
Gelatin (UNII: 2G86QN327L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSE 2208 (3 MPAS) (UNII: 9H4L9160BU)	

Magnesium Oxide (UNII: 3A3U0GI71G)
MAGNESIUM STEARATE (UNII: 70097M6I30)
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:2) (UNII: 5KY68S2577)
Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Type A (UNII: NX76LV5T8J)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
Polysorbate 80 (UNII: 6OZP39ZG8H)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
FERRIC OXIDE RED (UNII: 1K09F3G675)
SHELLAC (UNII: 46N107B71O)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
RAW SUGAR (UNII: 8M707QY5GH)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
Sodium Lauryl Sulfate (UNII: 368GB5141J)

Product Characteristics

Color	WHITE, PINK	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	OMP20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59450-012-27	2 in 1 CARTON	01/01/2016	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59450-012-01	3 in 1 CARTON	01/01/2016	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078878	01/01/2016	

Labeler - The Kroger Co. (006999528)